Teriflunomide Dr. Reddys 14 mg film-coated tablets

teriflunomide

HEALTHCARE PROFESSIONAL EDUCATION/DISCUSSION GUIDE: MALTA

Patient's name:	Patient's age:
Date of first visit:	Patient's gender: □ Male □ Female
Date first prescribed:	Today's date:

Discuss the following risks with the patient/parent/carer, explain the monitoring requirements and tell them what they should do if patients experience specific signs or symptoms.

Please read the SPC for full prescribing information

Discuss

Risk of haematological effects

Risk of decreased blood cells (affecting mainly white blood cells).

Full blood count before treatment initiation and thereafter if necessary, based on clinical signs or symptoms during treatment.

Risk of hypertension

Check blood pressure before treatment initiation and periodically during treatment.

Blood pressure elevation should be appropriately managed before and during treatment.

Risk of liver effects

Check liver function before treatment initiation and periodically during treatment.

Patients should be counselled on the signs and symptoms of liver effects and told to contact their doctor immediately if any develop.

Risk of serious infections

Patients should be told to contact their doctor immediately if they have any signs or symptoms of an infection.

Patients should also inform their doctor if they are prescribed or taking any other medicines that affect the immune system.

Consider an accelerated elimination procedure in case of a serious infection.

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Risk of teratogenicity

Inform women of childbearing potential (WOCBP) that teriflunomide can cause serious birth defects so it is contraindicated in pregnancy, and they must use effective contraception during and after treatment until their teriflunomide blood levels are low. Women should contact their doctor immediately if they plan to conceive, stop or change contraception during this time.

Check the potential for pregnancy in all female patients before and during treatment.

Tell the parents/carers of girls that they should contact their doctor for counselling on the risk of teratogenicity and contraceptive advice when she starts to menstruate.

If female patients become pregnant despite using contraceptive measures, they should stop teriflunomide and contact their doctor immediately who should:

o Consider and discuss with the patient the accelerated elimination procedure,
o Report any pregnancy case to Dr.Reddy's by calling: Tel: 01748 828 873 or visiting Spanish Pharmacovigilance System for Medicinal Products for Human Use: https://www.notificaram.es irrespective of adverse outcome
o Contact Dr.Reddy's for information regarding the measurement of teriflunomide plasma concentration.

Counsel & hand-over

Patient Card:

Provide the patient with the patient card and discuss the content regularly during each consultation and **at least annually during treatment**.

Complete your contact details on the patient card and replace it as necessary.

Educate the patient to show this card to any doctor or healthcare professional involved in medical care (e.g. in case of an emergency).

Advise the patient to contact their prescriber or general practitioner if they develop any signs or symptoms of the risks discussed in the patient card.

Discuss and Counsel & inform before treatment and regularly thereafter WOCBP including adolescents/their parents/caregivers about potential risk for the foetus.

Ensure adequate monitoring of patients when new prescriptions are issued including adverse reaction checks, and risk assessments and prevention.

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Suspected adverse reactions that may occur during treatment should be reported via adverse drug reactions (ADRs) to Malta Medicine Authority via the ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal.

For further information regarding this medication please contact local representative: EJ Busuttil Ltd.

Phone: 21447184 (service is available 24/7)

Email: safety@ejbusuttil.com

Office Adress:

Busuttil Buildings, Triq l-Għadam,

Central Business District Zone 1,

Birkirkara CBD1060 MALTA

When reporting please provide as much information as possible. By reporting side effects, you can help provide more information on the safety of this medicine.

Suspected adverse reactions should also be reported to Dr.Reddy's: Tel: 01748 828 873.

Email: drreddysgb@eu.propharmagroup.com

The patient has been informed about and understands the above mentioned risks and benefits associated with this treatment

Prescriber's name: Prescriber's signature:

The educational material has been prepared with the aim of ensuring safe and efficient use of the medication and adequate risk management and it has been approved by Malta Medicines Authority on 05/05/2025.